IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

GENUS MEDICAL TECHNOLOGIES, LLC,	)	
Plaintiff,	)	**Case No. 4:19-cv-03150-SEP**
v.	)	**JURY TRIAL DEMANDED**
BRACCO DIAGNOSTICS, INC., E-Z-EM, INC., E-Z-EM CANADA, INC.,	)	
and	)	
UNITED MINERALS AND PROPERTIES, INC.,	)	
Defendants.	)	

PLAINTIFF GENUS MEDICAL TECHNOLOGIES, LLC'S
OPPOSITION TO DEFENDANTS' JOINT MOTION
FOR SUMMARY JUDGMENT
OR SUMMARY ADJUDICATION

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INTRODUCTION

Bracco Bracco Diagnostics, Inc., E-Z-EM, Inc., and E-Z-EM Canada, Inc. ("Bracco") are part of an Italian conglomerate made up of various pharmaceutical companies around the world, and the self-proclaimed foundation[1] of its U.S. business is barium-sulfate suspension products ("BSSPs") used as contrast agents in medical imaging. [redacted]

Defendants' Memorandum in support of their motion for summary judgment tries to obscure the issues presented through numerous factual inaccuracies and distortions, but there is ample evidence to demonstrate antitrust violations and injury, and Genus's damages caused by Defendants' anticompetitive conduct. In particular, Genus's evidence will show:

- The relevant market consists solely of BSSPs. There are no price-sensitive substitutes, and the non-barium alternative contrast agents have distinct characteristics and some unique functions. Indeed, the FTC recognized a distinct market for "barium diagnostic products and related accessories" in 1990 in response to a proposed merger involving Bracco

[1] *See* SAF ¶214, 223 (PX30, PX249)

[2] *See* SAF ¶237 (PX227 at 10463).

subsidiary and Defendant here, E-Z-EM, Inc. *In the Matter of E-Z-Em, Inc., et al.*, 113 F.T.C. 945 (1990).

- [redacted]
- The upstream market for the needed barium-sulfate ingredient is also well-defined. In order to compete to any significant degree in the U.S. BSSPs market, a product must be approved by the FDA, and that requires that the source for the barium-sulfate ingredient be FDA registered for barium sulfate. It is undisputed that Cimbar is the only such manufacturer in the world.
- [redacted]. This precluded and continues to preclude Genus from obtaining FDA approval, thereby relegating Genus to an insignificant market share.
- There is no procompetitive justification for Defendants' exclusive arrangement. Although Defendants argue [redacted]. In any event, Defendants had less restrictive means of achieving their alleged procompetitive ends, including mechanisms that would give Bracco priority and/or have Genus pay for the use of the necessary data, collect the

ingredient data itself, or contribute to manufacturing and testing for Cimbar's ingredients.

- Genus can establish non-speculative damages caused by Defendants' conduct. Genus could have obtained the necessary funding for FDA approval through investors or loans, and its experience shows it could have attracted customers were its products FDA approved.

Bracco's monopoly has gone on long enough – since approximately 2010 – and it is now time for the Court to deny Defendants' last-ditch effort to avoid a trial in this matter.

BACKGROUND

A. A Significant Entry Barrier in the U.S. BSSPs Market Protects Bracco's Dominant Market Share.

[redacted][4]

[3] Genus cites its exhibits as "PX__." Transcripts, expert reports, contracts, and written discovery answers generally have the earliest exhibit numbers. Expert reports are cited by page number unless otherwise noted. Genus incorporates by reference its Response to Defendants' Statement of Material Facts ("RSMF") and Statement of Additional Material Facts ("SAF").

[4] It is undisputed that, to secure FDA drug approval, one must submit information to FDA on how the active pharmaceutical ingredients (API) in a product are manufactured. RSMF ¶170-72. The parties also do not dispute that barium sulfate is the API used in BSSPs. *See* RSMF ¶26, 190.

[redacted]

B. Bracco and Cimbar Blocked Genus's Path to FDA Approval by Refusing Access to Cimbar Products and/or Data.

[redacted]

[redacted]

[5] Defendants' Memorandum of Law in Support of their summary judgment motion is cited as "Mem."

C. There Are Dozens or Hundreds of Facts in Dispute Precluding Summary Judgment.

Defendants have filed a 56-page Memorandum and a 69-page statement of allegedly undisputed material facts ("SUMF") containing 212 purported facts, many of which are improper, lengthy paragraphs of additional argument. Both documents are full of factual mischaracterizations and ignore myriad ways in which material facts are in dispute. For ease of the Court's review, the following chart identifies the most important material fact disputes and lists the factual contentions supported in Genus's RSMF that undercut the core arguments in Defendants' Motion:

Facts Disputing Defendants' Faulty Arguments and Contentions	Responses to Defendants' Statement of Facts Showing the Existence of Genuine Fact Disputes
1. BSSPs are the relevant market.	RSMF ¶126-27, 129, 130-32, 135-36, 146-47
2. Bariscan is not proprietary to Bracco.	RSMF ¶13, 15-16, 23-24, 26, 34, 36, 38-40, 42, 92
3. Cimbar could and would have built its plant without its exclusive arrangement with Bracco.	RSMF ¶11, 13, 15, 18-19, 24, 33-34, 36, 44, 161-63
4. [redacted]	RSMF ¶15-16, 19, 23, 26-27, 30-31, 33-37, 48, 87-88, 161-62
5. [redacted]	RSMF ¶13, 103, 105
6. [redacted]	RSMF ¶13, 188
7. Cimbar has the data relating to Miti-Wite that Genus requested.	RSMF ¶89-95, 173-74, 181-82, 185-86, 191
8. The data relating to Miti-Wite exists and/or could be reasonably assembled.	RSMF ¶98, 173, 181, 185, 191-92
9. Bariscan and Miti-Wite are the same product.	RSMF ¶36, 89-96, 99-100, 106, 173, 175, 181, 187-90
10. [redacted]	RSMF ¶131-32, 140, 146-47, 156-58, 159-60
11. [redacted]	RSMF ¶194, 198, 201-02, 204-05, 206-07, 209, 212
12. Defendants' arrangement does not benefit competition.	RSMF ¶44, 161-68
13. Warning Letter to Genus has not remained in effect.	RSMF ¶4, 50, 72-78
14. Genus has followed FDA requirements.	RSMF ¶29, 32, 50, 55, 68-69, 72-76, 78
15. Genus has the ability to get FDA approval.	RSMF ¶176-80

16. There are no reasonable substitutes for barium sulfate manufactured by Cimbar.	RSMF ¶112-120, 137

LEGAL STANDARD

Summary judgment is only proper where the record, viewed in the light most favorable to the nonmoving party and giving that party the benefit of all reasonable inferences, shows that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. *See Nunn v. Noodles & Co.*, 674 F.3d 910, 913-14 (8th Cir. 2012); Fed. R. Civ. P. 56(c). "Material facts are those that might affect the outcome of the suit under the governing law, and there is a genuine dispute where a reasonable jury could return a verdict for the nonmoving party." *Rehkemper & Sons, Inc. v. Mid-Rivers Dev. and Constr., LLC*, 2023 WL 1388512, at *2 (E.D. Mo. Jan. 31, 2023) (citation and internal quotation marks omitted).

A court faced with a motion for summary judgment "should not weigh the evidence, make credibility determinations, or attempt to determine the truth of the matter." *Leonetti's Frozen Foods, Inc. v. Rew Mktg., Inc.*, 887 F.3d 438, 442 (8th Cir. 2018) (citations and internal quotation marks omitted). Rather, the court must consider the record "to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). The moving party bears the burden of establishing both that no genuine issue of material fact exists and that it is entitled to judgment as a matter of law. *McIntosh v. Monsanto Co.*, 462 F. Supp. 2d 1025, 1027-28 (E.D. Mo. 2006) (denying motion for summary judgment in antitrust case (citations omitted)). "Once the moving party has met this burden, the non-moving party…must set forth specific facts showing that a genuine issue of material fact exists." *Id.* (citation omitted). If a genuine issue of material fact exists, then summary judgment should not be granted. *Anderson*, 477 U.S. at 248.

ARGUMENT

I. Defendants' Apparent Suggestion that Summary Judgment Should be Granted More Freely in Antitrust Cases is Unsupported by the Law in this Circuit.

Contrary to Defendants' suggestion, [redacted] Defendants contend that [redacted]. But they cite no authority standing for such a proposition or data on [redacted]. The truth is that summary judgment is often denied in the antitrust context, just as it is in any other kind of case. The Supreme Court has held that there is "no special burden on plaintiffs facing summary judgment in antitrust cases." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 468 (1992). Accordingly, the Eighth Circuit holds that courts should "apply the same standard—whether the record reveals a genuine dispute of material fact—to antitrust and non-antitrust cases alike, neither favoring nor disfavoring summary judgment, but simply following the evidence (or lack thereof) and the law wherever they lead." *In re Wholesale Grocery Prods. Antitrust Litig.*, 752 F.3d 728, 732-33 (8th Cir. 2014) (reversing in part summary judgment).

Thus, while Defendants' Eighth Circuit cases [redacted]. Defendants' out-of-circuit cases, Mem. 7-8 (citing *Sanofi-Aventis U.S., LLC v. Mylan, Inc. (In re Epipen (Epinephrine Injection, Usp) Mktg., Sales Practices & Antitrust Litig.)*, 44 F.4th 959, 980 (10th Cir. 2022); *Cash & Henderson Drugs, Inc. v. Johnson & Johnson*, 799 F.3d 202, 209 (2d Cir. 2015)) are not binding, And, the single Eighth Circuit case specifically cited for this proposition, *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242 (8th Cir. 1988), does ***not*** suggest [redacted] Rather, *Archer-Daniels-Midland Co.* recites

the familiar standard that summary judgment may only be granted if a party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id*. at 245 (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). Genus can prove the elements of its claims and show the existence of material fact issues; nothing else is required. Summary judgment should be denied.

II. Genus Can Prove Every Element of Its Section 1 Claims, and Defendants' Challenges Are Based on Disputed Facts.

Genus can prove all essential elements of its claim under Section 1 of the Sherman Act. Specifically, Genus can show a relevant product market (consisting of BSSPs); that Bracco has

[redacted]

Vertical exclusive-dealing agreements between manufacturers and suppliers are analyzed under the rule of reason, which weighs the circumstances in assessing whether the agreement unreasonably restrains competition. *See Insignia Sys., Inc. v. News Am. Mktg. In-Store Inc.*, 661 F. Supp. 2d 1039, 1063-64 (D. Minn. 2009); *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1058-59 (8th Cir. 2000). To do so, a court considers (a) the agreement's duration, (b) the height of entry barriers to the market, and (c) whether the agreement forecloses a substantial share of the market. *Concord Boat*, 207 F.3d at 1059. A plaintiff meets its initial burden by showing either a defendant's market power or detrimental effects on competition, which shifts the burden to the defendant to demonstrate procompetitive effects. *Flegel v. Christian Hosp., Ne.-Nw.*, 4 F.3d 682, 688 (8th Cir. 1993). If the defendant does so, the burden shifts back to the plaintiff "to show that any legitimate objectives can be achieved in a substantially less restrictive manner, and the

court then weighs 'the harms and benefits to determine if the behavior is reasonable on balance.'" *Id.* (citation omitted). Genus can make these necessary showings.

A. BSSPs Comprise the Relevant Downstream Product Market.

Genus can show that BSSPs comprise a relevant antitrust market. As an initial matter, Defendants' contention that Genus "cannot prove a relevant product market," Mem. 10-16, overlooks the all-important fact that Genus need not do so at this stage; it simply needs to prove there is a genuine issue of material fact for the jury to resolve. *Contico Int'l v. Rubbermaid, Inc.*, 801 F. Supp. 280, 282 (E.D. Mo. 1992) (explaining that "[d]etermination of a relevant product market is generally a fact question," and, thus, summary judgment is appropriate only when the plaintiff "fail[s] to present an issue of fact for the jury on this matter"); *see also Insignia Sys.*, 661 F. Supp. 2d at 1059 (denying summary judgment where "both parties have brought forth evidence supporting their proposed relevant markets"). Genus more than meets that test and can easily establish that the relevant product market consists of BSSPs.

Defendants contest Genus's market definition, but their arguments rest on an overly simplistic view of competition and unsupportable legal principles. As shown in the chart below, Defendants argue that [redacted]

BSSP Category	Defendants' Proposed Market	Current Genus Products	Current Bracco Products	Purported Alternatives
[redacted]				

[6] The Court should reject Defendants' suggestion that [redacted] *See SuperTurf, Inc. v. Monsanto Co.*, 660 F.2d 1275, 1278 (8th Cir. 1981) ("In our view, 'submarket' analysis is particularly appropriate where, as here, a manufactured product allegedly 'competes' with an unlimited or virtually unlimited natural resource."). [redacted] RSMF ¶128-129.

[redacted]

These definitions rest on the assumption that an antitrust market is defined by functionality, that is, that the relevant market includes all products that can be used for the same purpose. As discussed below, however, that is not the law, and they cite no authority otherwise.

In short, market definition rests on more than Defendants' superficial focus on product function. The mere fact that two products "at some level compete with one another" does *not* necessarily put them in the same product market. *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 157-59 (D.D.C. 2000) (finding the relevant market to be "loose leaf chewing tobacco" instead of the "broader, smokeless tobacco market"). The question, therefore, is not simply whether the products generally compete. The key issue is whether consumers "shift from one product to the other in response to changes in their relative costs." *FTC v. Sanford Health*, 926 F.3d 959, 964 (8th Cir. 2019).

To answer that question, courts consider *both* qualitative and quantitative approaches to defining the relevant product market. *FTC v. Peabody Energy Corp.*, 492 F. Supp. 3d 865, 885 (E.D. Mo. 2020) ("*Peabody*"). Thus, courts weigh "practical indicia" identified by the Supreme Court in *Brown Shoe Co. v. U.S.*, 370 U.S. 294 (1962), including "industry or public recognition

[7] Defendants acknowledge home-brew solutions are "BSSP products," SUMF ¶149, and they do not identify any reasonable substitutes for BSSPs for swallow studies. *See* SUMF ¶148-52.

of the products as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Id.* "Defendants' business records are 'strong evidence' for defining the relevant product market" under this qualitative approach. *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 193-94 (D.D.C. 2017) (citations omitted); *see also Peabody*, 492 F. Supp. 3d at 885. Defendants do not even attempt to show how any of these *Brown Shoe* factors support their proposed market definitions.

Instead, Defendants argue that Genus's market definition fails because it has not shown that a BSSPs-only market satisfies the "hypothetical monopolist test" (HMT). Mem. 11-12. That test asks whether two products are price-sensitive, such that raising prices for one drives customers to the other. *See Swedish Match*, 131 F. Supp. 2d at 160. More basically, the HMT considers whether a hypothetical monopolist could profitably raise the price of a product by a small but significant and non-transitory increase ("SSNIP"), *Sanford Health*, 926 F.3d at 963, which is typically five percent. *Peabody*, 492 F. Supp. 3d at 904. [redacted] While the HMT can be useful in defining a market, *Anthem*, 236 F. Supp. 3d at 194, this Court has explained that "the HMT is not the only method for determining a relevant product market." *Peabody*, 492 F. Supp. 3d at 892. Thus, contrary to Defendants' suggestion, Genus's reliance on evidence outside the HMT cannot support summary judgment.

When all of the factors are considered, Genus easily can show that the relevant product market should be limited to BSSPs. As explained below, non-barium alternatives are not price-sensitive substitutes for BSSPs, and market participants—and the government—recognize that BSSPs form a distinct market. At the very least, the evidence indicates that there are numerous

fact disputes regarding the nature of the competition between BSSPs and non-barium alternatives that defeat summary judgment.

i. Bracco's Continuous Price Increases Reflect that BSSPs and Their Alternatives Are Not Price-Sensitive.

Bracco [redacted]. Therefore, BSSPs belong to their own market, under either the HMT or a *Brown Shoe* assessment of price sensitivity. *Peabody*, 492 F. Supp. 3d at 892 (price-sensitivity is a factor in market definition); *Swedish Match*, 131 F. Supp. 2d at 160 (calling the HMT a "way to evaluate price sensitivity").

First, Bracco [redacted]

[redacted]

RSMF ¶132 140; (PX16 Meyendorff Rep. 44, 48). [redacted]

[redacted]

[redacted][8] [redacted]

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8 [redacted] *See Bracco Diagnostics, Inc. v. Amersham Health*, Inc., 627 F. Supp. 2d 384, 438 n.232, 492-93 (D. NJ. 2009) (ruling on counterclaim).

9 *See* [redacted]

[redacted]. *See id.* (PX82).

Second, [redacted]

RSMF ¶132, ¶158-60 (Meyendorff Rep. 55-57). [redacted]

[redacted] *Id.*; SUMF ¶154.[10]

[redacted] Even a monopolist can raise prices only so high before driving customers to inferior options. "[C]ross-elasticity of demand" among products may "be the product of monopoly power rather than a belief on the part of consumers that the products are good substitutes for one another" because "[a]t a high enough price even poor substitutes look good to the consumer." *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 667 (D. Conn. 2016) (citation omitted).

[redacted]

[10] [redacted] RSMF ¶132.

[redacted]

ii. Factors Other Than Price Dictate Customer Choice.

The fact that BSSPs and non-barium alternatives are not price-sensitive is also supported by evidence of other factors driving customer choice. Any customer shift from BSSPs to alternatives like iodinated products does not prove that they are price-sensitive substitutes. Rather, customer choice is driven by factors that (a) are unrelated to price and (b) reflect *Brown Shoe* "practical indicia" for defining a market—including "distinct customers" and "peculiar characteristics and uses." *Brown Shoe*, 370 U.S. at 325. These factors include (RSMF ¶129):

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

Defendants' cases do not suggest otherwise. In contrast to insignificant differences between products in those cases, *e.g. Craftsmen Limousine, Inc. v. Ford Motor Co.*, 491 F.3d 380, 384 (8th Cir. 2007) (limousines of lengths ten inches apart), these non-price distinctions between BSSPs and iodinated products are not only meaningful, but frequently mandate customer choice. RSMF ¶129, 135.

iii. Bracco and the Public Have Treated BSSPs as Unique, and the FTC Recognized the Barium Contrast Market in a Complaint Against E-Z-EM.

A separate *Brown Shoe* factor in market definition is how industry and the public view the proposed market. *See Peabody*, 492 F. Supp. 3d at 894-95. Relevant evidence in this inquiry includes parties' "ordinary course documents." *Id.* Again, this factor supports Genus's market definition. [redacted]

In 1990, the FTC recognized the barium contrast market as its own economic entity. RSMF ¶129. In particular, the FTC brought a complaint against Defendant E-Z-EM to reverse its acquisition of Lafayette Pharmacal, Inc.'s barium diagnostic products business, asserting that E-Z-EM "ha[d] acquired a monopoly in the relevant market in the barium business in the United States." *In the Matter of E-Z-Em, Inc., et al.*, 113 F.T.C. 945 (1990). To resolve the matter, E-Z-EM divested the Lafayette business and consented to other limitations on its involvement in the "barium diagnostic products business in the United States." *Id.*

[redacted].

[redacted]

iv. **Additional Evidence Shows Bowel Distension BSSPs Have No Price-Sensitive Substitutes.**

Defendants' arguments regarding the bowel-distension category do not establish that BSSPs have price-sensitive substitutes, and, in any event, they are based on a mischaracterization

of the opinion of Genus's antitrust expert, Dr. Howard Marvel. *Cf.* Mem. 3, 15, 23, 55. *First*, [redacted]

See Swedish Match, 131 F. Supp. 2d at 160.

Second, [redacted].

[redacted] At the very least, there is a material fact dispute regarding competition and possible substitutes in this category.

v. Dr. Marvel Cited Compelling Evidence Supporting Genus's Market Definition.

Genus's BSSP-only market definition is also supported by Dr. Marvel's opinion. Defendants claim Dr. Marvel's market-definition opinion is insufficient because he purportedly "ignored" the HMT. Mem. 12. As explained more fully in Genus's response to Defendants' motion to exclude Dr. Marvel, parties are not required to rely on a quantitative approach to define a market. *See, e.g. McWane, Inc. v. FTC*, 783 F.3d 814, 829-30 (11th Cir. 2015); *Apple iPod iTunes Antitrust Litig.*, 2014 WL 4809288, *7 (N.D. Cal. 2014). [redacted]

And, in any event, market definition is not always decided based on expert opinions. *See Swedish Match*, 131 F. Supp. 2d at 162 (finding parties' experts unpersuasive and defining the market based on other evidence).

vi. Genus's Case is Unchanged Whether There Are One or Four BSSP Markets.

Defendants argue that Genus's market definition is improper because it combines four separate categories of BSSPs that are not substitutes for one another. Mem. 16. Defendants miss the mark. *First*, [redacted]

[11] *Id.* at 125:22-126:9 [redacted] (emphasis added).

[redacted]

PX03 Marvel Dep. 40:13-19. [redacted]

[redacted] *See* Mem. 16.

Second, even if there were a flaw in Genus's market definition, it would not follow that Defendants are entitled to summary judgment. The Eighth Circuit has observed that "'[m]arket definition is not a jurisdictional prerequisite, or an issue having its own significance under the [Sherman Act]; it is merely an aid for determining whether power exists.'" *Gen. Indus. Corp. v. Hartz Mountain Corp.*, 810 F.2d 795, 805 (8th Cir. 1987) (quoted in *Bard I*, 657 F. Supp. 2d at 1095 n.36). Moreover, courts have considered revised relevant product-market definitions, either of the court's own making or as proffered by plaintiffs opposing summary judgment. *See Bard I*, 657 F. Supp. 2d at 1095-96 (considering the court's own market definitions after rejecting plaintiffs'); *cf. Contico*, 801 F. Supp. at 283 (noting plaintiff's failure to propose an alternative market definition "[i]n the face of a summary judgment motion").[12]

[12] Defendants' reliance on *Contico* is misplaced. Contico defined its relevant market as "molded plastic products" from its catalogs, which included items as diverse as bins, lawn and garden sprayers, hose reels,

B. Cimbar Is the Only Participant in the Relevant "Upstream" Market.

Defendants' argument that Genus improperly limits the "upstream" market to Cimbar's barium sulfate, Mem. 16-17, ignores the essence of the anticompetitive conduct at issue here. As an initial matter, Genus is not asserting any claim that Cimbar's market is being illegally restrained, and Defendants cite no authority suggesting that Genus must define this upstream market with the same precision that it defines the market being illegally restrained. Nevertheless, Genus can readily define the relevant upstream market, and Cimbar is its only participant.

[redacted] *Cf. Microbix Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F. Supp. 2d 680 (D. Md. 2000), *aff'd*, 11 F. App'x 279 (4th Cir. 2001) (declining to treat alternative suppliers as substitutes for FDA-approved suppliers in the context of assessing anticompetitive effects instead of market definition).

[redacted]

mops, and luggage carriers. *Id*. at 282. Such varied products were only linked by "the material out of which they are made." *Id*. at 283. By contrast, BSSPs are all oral contrast media used in radiographic imaging procedures. This market is narrower than *Contico*'s, and it easily divides into four identifiable submarkets.

[redacted]

The fact that the market consists of only one participant does not change the analysis. The Supreme Court has explicitly rejected the argument that "as a matter of law, a single brand of a product or service can never be a relevant market under the Sherman Act," explaining that "in some instances one brand of a product can constitute a separate market." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 481-82 (1992). Courts confronting this question have emphasized that the answer depends on the specific facts of the case. *See US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 66 (2d Cir. 2019) (reversing dismissal where plaintiff "successfully alleged that the Sabre platform is not interchangeable with other booking alternatives"). Here, firms which do not have the necessary registration cannot supply a Bracco competitor with barium sulfate that could be used in an FDA-approvable BSSP. Therefore, the upstream market in this case *must* be limited to Cimbar's barium sulfate products—there ***is no reasonable substitute.***

[redacted]

13 [redacted]

C. Bracco Has Market and Monopoly Power.[14]

As this Court has held, "To carry its burden under the rule of reason, a plaintiff must demonstrate either (a) market power and the defendant's power within that market; or (b) actual detrimental effects to competition." ECF 115 at 35; *see Flegel*, 4 F.3d at 688. A defendant "has market power if it has the ability 'to raise price above the competitive level without losing so many sales so rapidly that the price increase is unprofitable and must be rescinded.'" *Craftsmen*, 491 F.3d at 388 (citations omitted). An inference of market power may be drawn from a defendant's high percentage of market share. *See Mo. Hosp. v. C.R. Bard, Inc.*, 2008 WL 199567, at *6 (E.D. Mo. Jan. 22, 2008). Similar considerations establish that a defendant possesses "monopoly power" in the relevant market as required for a Section 2 claim. ECF 115 at 48 (quoting *Se. Mo. Hosp.*, 2008 WL 199567, at *5). Monopoly power is "the power to control prices or exclude competition," which "ordinarily may be inferred from the predominant share of the market." *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966) (citation omitted).

Genus can prove that Bracco has market power (under Section 1) and monopoly power (under Section 2) in the BSSP market. In particular, [redacted].[15] At the very least, there are material fact disputes regarding Bracco's market/monopoly power, and, therefore, summary

[14] "Market power" as required for a Section 1 claim and "monopoly power" as required for a monopolization claim under Section 2 are based on similar and often overlapping considerations. In the interest of efficiency, Genus addresses both elements in this section and, as explained below, has sufficient evidence to satisfy even the more demanding "monopoly power" standard.

[15] [redacted]

judgment is inappropriate.

i. Bracco's Continuous Price Increases Reflect its Market and Monopoly Power.

Despite Defendants' argument to the contrary, Mem. 39, [redacted]. A hallmark of market power is the ability to profitably raise prices to a supracompetitive level. *See Craftsmen*, 491 F.3d at 388. Monopoly power is similarly defined. *See Process Controls Int'l, Inc. v. Emerson Process Mgmt.*, 753 F. Supp. 2d 912, 925 (E.D. Mo. 2010). [redacted] This is entirely consistent with a monopolist significantly raising prices as far as they can go (when unrivaled) and maintaining them above the competitive level even after a competitor emerged.[17]

[redacted]

[16] [redacted].

[17] *See* PX18 Marvel Rep. 41 (noting that a "signifier of monopoly power" is "an established monopolist retains high prices in the face of declining demand while limiting investment").

[redacted]

Second, [redacted]

Third, [redacted]

[redacted]. "The picture is one of a manufacturer that sets prices with little concern for its competitors, 'something a firm without a monopoly would have been unable to do.'" *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) (citation omitted). [redacted]

Finally, [redacted]

ii. Bracco Has an Overwhelming Market Share in the BSSP Market.

Bracco's market and monopoly power is also evident [redacted]). Courts have held that "market share of over 70 percent is usually 'strong evidence' of monopoly power," *Tops Markets, Inc. v. Quality Markets, Inc.*, 142 F.3d 90, 99 (2d Cir. 1998); and that 65% market share creates a "rebuttable presumption of market power," *Masimo Corp. v. Tyco Health Care Grp., L.P.*, 2006 WL 1236666, at *11 (C.D. Cal. Mar. 22, 2006), *aff'd*, 350 F. App'x 95 (9th Cir. 2009).

[redacted]

D. Genus Can Show Harm to Competition and Consumers.

i. Defendants Have Substantially Foreclosed the Market.

Defendants suggest [redacted] but they rely on an improper legal standard. "The test is not total foreclosure," or whether a defendant's competitor can still "survive," but whether defendants' conduct "bar[s] a substantial number of rivals or severely restrict[s] the market's ambit." *Dentsply Int'l*, 399 F.3d at 191. "Substantial foreclosure" exists where a dominant firm prevents its potential rivals from ever reaching "the critical level necessary" to pose a real threat to its business. *ZF*

[18] [redacted]

Meritor, LLC v. Eaton Corp., 696 F.3d 254, 286 (3d Cir. 2012). "Traditionally a foreclosure percentage of at least 40% has been a threshold for liability in exclusive dealing cases," though some courts require a "lesser degree of foreclosure" when the "defendant is a monopolist." *McWane*, 783 F.3d at 837. Indeed, market foreclosure can exist even when competitors grow. *See In re Keurig Antitrust Litig.*, 383 F. Supp. 3d 187, 235-36 (S.D.N.Y. 2019) (declining to dismiss claim).

T[redacted]

For this reason, Defendants' cases are simply inapposite. Both *Roland Machinery Co. v. Dresser Industries, Inc.*, 749 F.2d 380, 394 (7th Cir. 1984), and *Omega Environmental, Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1162-63 (9th Cir. 1997), held that exclusive-dealing arrangements regarding product distribution did not impermissibly foreclose the market for rival manufacturers' products because those manufacturers had sufficient avenues for reaching consumers and gaining a market share. [redacted]

[redacted] Under the standards in *Roland Machine* and *Omega Environmental*, this is sufficient to establish market foreclosure.

ii. The *Tampa Electric* Factors Show Defendants' Arrangement is Exclusionary.

In addition, the three factors identified in *Tampa Electric Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961), to evaluate an exclusive-dealing agreement – entry barriers, market foreclosure, and duration – all favor Genus and indicate Defendants' arrangement is anticompetitive.

1. There Are High Barriers to Market Entry.

The evidence shows that there are high barriers to entry in the BSSP market, or at the very least, that there are relevant material fact disputes. As an initial matter, Defendants' argument that there are no significant entry barriers (Mem. 22-24) rests on two faulty concepts. *First*, Defendants rely on their overly expansive market definitions that include non-barium products, and they do not address the unique issues facing BSSPs. *Second*, [redacted] On the contrary, Genus has consistently argued that Defendants' MSA [redacted] *Concord Boat*, 207 F.3d at 1059 (rejecting claim because plaintiffs had "presented scant evidence" that "firms have difficulty entering" the market at issue).

The entry barriers here include the need for FDA approval to be acceptable to customers and (in turn) the need for a source of barium sulfate with which one can obtain that approval. The need to satisfy regulators is a cognizable barrier to market entry. *See Chicago Bridge & Iron Co.*

N.V. v. F.T.C., 534 F.3d 410, 438 (5th Cir. 2008) (need for regulatory experience with FERC was a barrier to market entry); *see also Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1439 n.11 (9th Cir. 1995) ("It is well known that some of the most insuperable barriers in the great race of competition are the result of government regulation." (citation omitted)); *S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co.*, 740 F.2d 980, 1002 (D.C. Cir. 1984) ("The costs and delays of the regulatory process clearly constitute barriers to entry" even though agencies, not defendant, were responsible for the costs and delays).

[redacted][19] Any would-be Bracco competitor would face the same barrier, and Defendants' conduct has prevented Genus, or any potential competitor, from surmounting this barrier and expanding in the market.

Defendants' cases do not hold otherwise. For example, Defendants suggest *St. Francis Med. Ctr. v. C.R. Bard, Inc.*, 657 F. Supp. 2d 1069 (E.D. Mo. 2009) (*Bard I*), [redacted] (quoting *id.* at 1101). But unlike *Bard I*, the barrier here is [redacted] but the [redacted]. And, regardless, *Bard I* concerned device approval, which is far less expensive than drug approval (PX18 Marvel Rep. 46), and as the Eighth Circuit has recognized, a "significant barrier to entry may exist when large amounts of capital would be required." *Concord Boat*, 207 F.3d at 1059. Similarly, *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98 (3d Cir. 1992), did not hold that FDA approval cannot be a barrier to entry, but instead found that a competitive market existed where the number of manufacturers and FDA-approved products in the market increased from 26 to 32 over a six-year period. *Id.* at 103. [redacted]

19 [redacted]

[redacted] *See Brooks v. Tri-Systems, Inc.,* 425 F.3d 1109, 1111 (8th Cir. 2005) (hearsay cannot be used to support or defeat a motion for summary judgment). [redacted].

2. Defendants' Market Foreclosure Significantly Limits Customer Choice.

The second *Tampa Electric* factor—market foreclosure—also demonstrates the anticompetitive nature of Defendants' agreement. Defendants argue [redacted] But courts have repeatedly found market foreclosure where customers had a technical choice between products but lacked practical options. As the Third Circuit has held, "[A] monopolist may use its power to break the competitive mechanism

[20] Defendants cite *Digene Corp. v. Third Wave Tech,, Inc.*, 323 F. App'x 902, 911 (Fed. Cir. 2009), for the proposition that "consumer preference for FDA-approved products [does not] constitute an entry barrier." Mem. at 24. But in holding that the counterclaim-defendant's "contracts did not have anticompetitive effect," the *Digene* court merely noted it was not the counter-claim defendant's "fault" that the counterclaim-plaintiff's product lacked FDA approval. The opinion does not indicate why the product did not have FDA approval. Here, in contrast, Defendants' MSA [redacted]

[21] Since Defendants twice address market foreclosure (making different arguments, Mem. at 18-21, 24-26), Genus does as well.

and deprive customers of the ability to make a meaningful choice." *ZF Meritor*, 696 F.3d at 254. Thus, in *ZF Meritor*, a dominant supplier of truck transmissions foreclosed the market by forcing long-term agreements on truck manufacturers who were concerned they would otherwise be unable to meet consumer demand. *Id*. at 258. Similarly, in *LePage's Inc. v. 3M*, a monopolist's use of bundled rebates foreclosed portions of the market to competitors that did not offer an equally diverse line of products. 324 F.3d 141, 154-58 (3d Cir. 2003). And, in *Dentsply*, a manufacturer of prefabricated teeth prohibited dealers from adding competing lines to their product offerings and could terminate dealer relationships at will. 399 F.3d at 185. "Although consumers had a choice between products in *LePage's, Dentsply,* and *ZF Meritor*, in each case the defendant's anticompetitive conduct rendered that choice meaningless." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 404 (3d Cir. 2016).

[redacted]

Defendants' argument that Genus cannot show market foreclosure because it was not prevented from finding a barium-sulfate supplier or developing its own source, Mem. 26, also

[22] Defendants also argue that customers can choose a non-barium product, Mem. 24-25, but such products fall outside the relevant market and are irrelevant here.

misunderstands antitrust law and Genus's argument. *First*, Genus was not required to develop its own source of barium sulfate. "[O]ne of the evils proscribed by the antitrust laws is the creation of entry barriers to potential competitors by requiring them to enter two markets simultaneously." *Eastman Kodak*, 504 U.S. at 485. *Second*, [redacted] *See Fresenius Kabi USA, LLC v. Par Sterile Prod., LLC*, 2017 WL 548944, at *3 (D.N.J. 2017) (substantial foreclosure adequately pled where defendants allegedly used exclusive-dealing agreements to block competitors' access to suppliers with an active FDA drug master file, thereby preventing competitors from obtaining FDA approval); *Microbix*, 172 F. Supp. 2d at 694 (rejecting argument that plaintiff challenging exclusive contract between monopolist and FDA-approved supplier should use another supplier).

3. The Duration of Defendants' Arrangement Is Anticompetitive.

Finally, the duration of Defendants' arrangement, the third *Tampa Electric* factor, also reflects that the agreement is anticompetitive. Mem. 26-28; RSMF ¶46-48. Exclusive-dealing contracts with terms between three and seven years have been found anticompetitive. *See ZF Meritor*, 696 F.3d at 287 (finding that five- and seven-year agreements were unlawful); *Roxul USA, Inc. v. Armstrong World Industries, Inc.*, 2019 WL 1109868 (D. Del. Mar. 8, 2019) (on summary judgment, finding genuine issue of fact existed as to whether three-year exclusivity contracts, which carried a "verbal understanding" that they would last indefinitely, were unlawful).

This standard is easily met here. [redacted]

[redacted]

iii. Genus Can Show Direct Harm to Competition.

Defendants claim that Genus cannot show "direct proof of harm to competition" such as increased prices or reduced output, Mem. 28, but the record shows otherwise. At the very least, there are material fact disputes which preclude summary judgment.

First, this case involves a two-player market where Defendants [redacted]. "When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, i.e. predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general." *LePage's*, 324 F.3d at 159 (emphasis added). "[E]ven the foreclosure of 'one significant competitor' from the market may lead to higher prices and reduced output." *Id.* (citation omitted); *see also* ECF 115 at 37. Defendants' market foreclosure is proof of harm to competition. *See id*.

Second, as the Court has recognized, "Price increases and reduced output are . . . not the only recognized types of antitrust injuries." ECF 115 at 26. Rather, antitrust injury also exists, for

example, where defendants attempt to delay a plaintiff's FDA approval. *See Fresenius*, 2017 WL 548944 (denying dismissal where defendants had exclusive-dealing agreements with manufacturers holding an active DMF that plaintiff needed to access to obtain FDA approval); *In re Suboxone Antitrust Litig.*, 622 F. Supp. 3d at 79 (fact issue precluded summary judgment on whether defendant's conduct delayed FDA approval and caused anticompetitive harm). Courts also have found a potential antitrust injury where defendants allegedly conspired to withhold necessary data from competitors to prevent competition. *See Choiceparts, LLC v. Gen. Motors Corp.*, 2005 WL 736021, at *8 (N.D. Ill. Mar. 30, 2005) (denying summary judgment where defendants allegedly conspired to withhold data plaintiff needed to develop its products so plaintiff could not compete with joint venture owned by defendants). The record shows both here.

Third, Bracco *has* increased prices. [redacted]

Finally, [redacted]

[redacted]

E. All Relevant Contractual Clauses Are Anticompetitive.

[redacted]

[redacted]

F. Defendants' Purported Procompetitive Objectives Could Be Achieved Through Less Restrictive Means, and Whether Defendants' Arrangement is "Reasonable on Balance" Is for the Jury to Decide.

Once a Section 1 plaintiff shows the defendant's market power or actual detrimental effects to competition, the burden shifts to the defendant to demonstrate procompetitive justifications for its conduct. *Flegel v. Christian Hosp., Ne.-Nw.*, 4 F.3d 682, 688 (8th Cir. 1993). If the defendant does so, the burden shifts back to the plaintiff "to show that any legitimate objectives can be achieved in a substantially less restrictive manner, and the court then weighs 'the harms and benefits to determine if the behavior is reasonable on balance.'" *Id.* (citation omitted).

As demonstrated above, Bracco has monopoly power, and Defendants' conduct has substantially foreclosed the BSSP market. Defendants thus bear the burden of identifying procompetitive effects of their arrangement. [redacted].[23] Mem. 32-33; *see* RSMF ¶44, 161-68. [redacted]

[23] [redacted]

[redacted]

As discussed below, fact issues exist as to whether Defendants' purported objectives could have been achieved through less restrictive means.[24] [redacted] And in any event, the Supreme Court has rejected the notion that an original manufacturer's free-riding concerns require a competitor to manufacture its own component parts. [redacted]

The existence of these less restrictive means demonstrates the invalidity of the "procompetitive" justifications posited by Defendants. Although they claim that [redacted]

[redacted]

[24] Defendants' reliance on Dr. Marvel's 40-year-old article on exclusive dealing, Mem. 29, is misplaced. As the passage they cite makes plain, the article addresses exclusive dealing in a different context: supplier-dealer agreements.

[redacted]. The ultimate question—whether the anticompetitive harms of Defendants' arrangement outweigh its purported procompetitive benefits—is thus for the jury. *See Geneva Pharm. Tech. Corp. v. Barr Labs Inc.*, 386 F.3d 485, 494 (2d Cir. 2004).

i. Defendants Had Less Restrictive Options.

Defendants could have pursued less restrictive means to achieve their purported procompetitive goals—including incentivizing investment, precluding freeriding on Defendants' investment, and providing a supply of BSSPs to consumers—rendering it a jury question whether their arrangement is reasonable on balance. *See* RSMF ¶163, 168. Genus would have explored all of these options with Cimbar had it been permitted to do so. SAF ¶257-59; Powers Dec. ¶30-31.

1. A Requirements Clause.

As noted, had Defendants [redacted].

Microbix is instructive. There, a supplier and a manufacturer entered an exclusive-supply agreement that allegedly restrained a generic drug market by denying the plaintiff "access to the only source of FDA-approved HNK cells." 172 F. Supp. 2d at 692. Among the legitimate business justifications the manufacturer cited for this arrangement were securing a stable and adequate

supply and "protecting its investment in [the supplier] and prevent[ing] free-riding by [plaintiff]" *id*. at 693. The court, however, determined that a "fact finder could conclude that the anti-competitive effects of Defendants' exclusive supply agreement outweigh any procompetitive virtues," *id*. at 695, specifically noting that the defendants did not need an exclusivity provision where a requirements clause would have sufficed:

> [C]ontrary to Defendants' contention, the exclusive agreement was not the only means for ensuring a steady supply of HNK cells. A requirements contract (as opposed to an exclusive arrangement) could have secured a stable supply of HNK cells that [manufacturer defendant] Abbott would need for its urokinase production. Such a contractual arrangement, without an exclusivity feature, would be adequate to protect Abbott's "investment" in [supplier defendant] BioWhittaker, because BioWhittaker would continue to satisfy Abbott's needs first. Since [plaintiff] Microbix would be allowed to purchase only the excess cells, there would be little, or no, "free riding."

Id. at 693. The court concluded that "summary judgment is inappropriate with respect to the issue of illegality under section 1." *Id*. at 695.[25]

[redacted]

[25] While the court granted summary judgment on causation and damages grounds, *Microbix* is distinguishable from this case on those issues. *See* Section II.H., *post*.

[26] [redacted]

[redacted]

27 [redacted]

28 [redacted]

[redacted] A requirements clause standing alone, then, would have been a less restrictive alternative to exclusivity, with greater procompetitive benefits.

2. Requiring Genus to Contribute or Pay a Premium.

As an initial matter, Defendants' "preventing free-riding" justification overstates Bracco's investments and its role in Cimbar's manufacturing process. RSMF ¶19, 30, 33-37, 44. Even beyond those factual disputes, the purported justification falters for at least two reasons. *First*, the Supreme Court rejected a similar argument in *Eastman Kodak*. There the defendant argued that its investment in manufacturing replacement parts for its equipment justified its control of the parts and service markets for that equipment. The Court dismissed the notion that would-be competitors in the service market ("ISO's") could simply manufacture their own parts:

> Kodak claims that its policies prevent ISO's from "exploit[ing] the investment Kodak has made in product development, manufacturing and equipment sales in order to take away Kodak's service revenues." … Kodak does not dispute that respondents invest substantially in the service market, with training of repair workers and investment in parts inventory. Instead, according to Kodak, the ISO's are free-riding because they have failed to enter the equipment and parts markets. *This understanding of free-riding has no support in our case law.* To the contrary, as the Court of Appeals noted, *one of the evils proscribed by the antitrust laws is the creation of entry barriers to potential competitors by requiring them to enter two markets simultaneously*.

Eastman Kodak, 504 U.S. at 485 (emphasis added) (footnote omitted). Likewise, Defendants' argument that [redacted]

In *Microbix,* the court rejected defendants' contention that the plaintiff could have relied on an alternative supply source—even though the plaintiff had represented to FDA that it could find one—because the defendant supplier was at that time the only source with FDA approval:

> Defendants ignore the fact that [supplier] BioWhittaker was the only supplier of *FDA-approved* HNK cells. It is undisputed that the "alternate" source cannot supply HNK cells until it has been qualified by the FDA. Given the uncertainty concerning the regulatory process (nationally and internationally) in qualifying such a source, and the need for funding necessary for qualification, one cannot reasonably deem the "alternate" source to be a substitute for the Cali [e.g., BioWhittaker's] source.

Id. at 694 (emphasis in original). Similarly, Defendants' arrangement [redacted] The fact remains that Cimbar is the only such registered manufacturer, making it the sole—and thus the only relevant—source of an ingredient for an FDA-approvable product. *See id*.

Second, Defendants' argument ignores that free-riding is not a concern when defendants can be compensated for their investments. "When payment is possible, free-riding is not a problem because the 'ride' is not free." *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 479-80 (7th Cir. 2020); *see also United States v. Microsoft Corp.*, 1998 WL 614485, at *21 (D.D.C. Sept. 14, 1998) (applying this rule in exclusive-dealing case). As the Ninth Circuit noted in the *Eastman Kodak* case, instead of refusing to sell parts to the ISO's, the defendant could have avoided free-riding by pricing its products to reflect its investment costs. *Image Tech. Serv., Inc. v. Eastman Kodak Co.*, 903 F.2d 612, 619 (9th Cir. 1990), *aff'd*, 504 U.S. 451 (1992).

Genus is hardly looking to "steal" the fruits of Bracco's investment. Mem. 34. It would have had to pay its own costs for seeking FDA approval using Cimbar's ingredients. PX18 Marvel Rep. 34, 36. [redacted]

[redacted] *See Image Tech.*, *id.*

Requiring Genus or another competitor to make its own investments and contributions (or buy barium sulfate at a premium), then, would have been a less restrictive alternative to Defendants' exclusivity agreement, undercutting their "[redacted]

3. Filing the DMF Defendants Contracted to File.

The DMF option that Defendants actually contracted for presents yet another less restrictive alternative to Defendants' arrangement, in particular with respect to [redacted]

[redacted]

Genus does not need to show that Defendants declined to file a DMF for an anticompetitive reason. *See Microbix*, 172 F. Supp. 2d at 695 (fact-finder could find defendants' exclusive agreement unreasonably anticompetitive regardless of whether defendants' "legitimate business reasons" were pretextual). Nevertheless, one can reasonably infer the decision was driven by Bracco's concern [redacted]. The FDA is indifferent as to whether data is filed with an NDA or through a DMF. PX17 Auchincloss Rep. 28. [redacted] RSMF ¶3. [redacted]

[29] *See also* PX17 Auchincloss Rep. 27-28 [redacted]

[redacted][30] SAF ¶217-18 (PX51; PX17 Auchincloss Rep. 28; PX08 Spinazzi Dep. 56:14-57:5; PX52).

4. Permitting Genus to Collect Bariscan or Miti-Wite Data.

As an alternative to filing a DMF, Defendants could have protected any proprietary information without a [redacted].

Defendants had several ways to provide Genus with Bariscan data outside of a DMF. [redacted]

[30] While Bracco's chief regulatory officer claims [redacted]

ii. Because Defendants Had Less Restrictive Ways to Achieve Their Purported Procompetitive Objectives, Weighing the Harms and Benefits of Their Arrangement Is for a Jury.

In similar circumstances, courts have deemed it a jury question whether the defendants' conduct was on balance anticompetitive and whether they had less restrictive alternatives. In *Geneva Pharm.*, 386 F.3d at 494, for example, a supplier and a manufacturer allegedly conspired to restrain trade and monopolize the downstream market for a generic drug through an exclusive arrangement. The defendants' supply agreement required the supplier to sell its chemical ingredient exclusively to the manufacturer (until another manufacturer began selling the generic drug) and required the manufacturer to purchase solely from the supplier. *Id*. at 491. The defendants' five-year confidentiality agreement barred either party from disclosing "valuable, proprietary, technical, commercial and other confidential information." *Id*. The plaintiffs argued that both agreements delayed their entry into the generic drug market. *Id.* at 494. The Second Circuit noted that exclusive-dealing agreements could have procompetitive purposes and effects, but it found "essential facts" in dispute surrounding whether the defendants' justifications were outweighed by anticompetitive effects. *Id*. at 509. In particular, the court stressed the factual dispute over whether the supplier was the "sole available supplier" of the drug's primary ingredient:

> [A]n exclusive dealing agreement that dedicated all that supply to one buyer could freeze out competition to an extent that greatly outweighed any pro-competitive effects. At the least, such a situation would heighten the need to consider if less restrictive means could have achieved the pro-competitive benefits of an exclusive dealing arrangement without totally foreclosing competition.

Id. (reversing in part summary judgment for defendants).

Geneva is on point here. Cimbar is the only supplier registered with the FDA specifically for barium sulfate and thus the only one currently positioned to help a BSSP manufacturer secure FDA approval. *See* PX20 Arrowsmith Adden. Defendants' exclusivity and confidentiality clauses,

like the ones in *Geneva*, are thus restraining the market, and it is a jury question whether their purported procompetitive benefits outweigh their "freez[ing] out" of competition. *See id*.

In fact, Defendants' arrangement is more exclusionary than the one in *Geneva*, as ([redacted] These differences underscore Defendants' less restrictive options outlined above (e.g., including a requirements clause but not an exclusivity provision, requiring Genus to contribute to manufacturing and/or testing, selling to Genus at a premium, filing a DMF, or permitting Genus to collect data at its own cost).

Microbix also demonstrates that a fact issue exists. As explained above, that case shows that Defendants did not need to include the exclusivity provision in the MSA because the requirements clause alone would have obligated Cimbar to prioritize Bracco's needs without barring Cimbar from selling to Bracco competitors. *See* 172 F. Supp. 2d at 693. The court determined that a "fact finder could conclude that the anti-competitive effects of Defendants' exclusive supply agreement outweigh any procompetitive virtues." *Id*. at 695. *See also Insignia Sys.* 661 F. Supp. 2d at 1063-65 (after concluding that plaintiff produced sufficient evidence that defendants' exclusive contracts substantially foreclosed the relevant market, the court declined to find as a matter of law that their procompetitive benefits outweighed their harms).

In performing its balancing test, the jury can also consider whether Defendants' purported procompetitive justifications remain valid grounds for continuing to withhold ingredients and data from Genus, even assuming they were valid at the onset of Defendants' arrangement. [redacted]

[redacted] Mem. 32. [redacted] *Cf. Roxul*, 2019 WL 1109868, at *18 (triable issue whether defendant's exclusive agreements with distributors were procompetitive where plaintiff invested in distributors even without exclusivity). [redacted]

But even assuming that exclusivity had some procompetitive justification at the onset, as Dr. Marvel has opined, any such justification ended before Genus entered the market. [redacted] Exclusivity was then purely anticompetitive and had "no pro-competitive justification," particularly after Bracco became a complete monopoly

in the BSSP market in 2010 and FDA guidance on unapproved drugs changed in 2011. *Id.* at 33; *see id.* at 31-36; PX03, Marvel Dep. 255:25-256:4; RSMF ¶161, 163.[31]

[redacted] These clauses are now purely anticompetitive. Further, it is meritless for Defendants to contend [redacted].

Along with the evidence and argument regarding the less restrictive options available to Defendants, Dr. Marvel's opinions belong in the mix for the jury to weigh whether Defendants' arrangement was on balance anticompetitive when Genus sought product and data from Cimbar. *See Roxul*, 2019 WL 1109868, at *18 (finding genuine fact issue whether defendants' exclusive dealing agreements had procompetitive benefits where plaintiff's expert opined otherwise).[32]

G. Defendants Cannot Justify Withholding Bariscan or Miti-Wite Data.

In a separate section, Defendants attempt to justify their agreement to withhold Miti-Wite data. Mem. 38-45; RSMF ¶169-75, 181-92. [redacted]

[31] *See also* [redacted]

[32] *Sewell Plastics, Inc. v. Coca-Cola Co.*, 720 F. Supp. 1196 (W.D.N.C. 1989), *aff'd*, 912 F.2d 463 (4th Cir. 1990), cited by Defendants, is inapposite. The plaintiff (a supplier) was not challenging Defendants' requirements contract (which was "not an *exclusive* dealing arrangement on its face") because it could not access a supply source; and that plaintiff (unlike Genus) could not even show an adverse impact on competition. *Id.*

[redacted]

[redacted] Those arguments fall short because (a) Genus can prove market power and detrimental effects (as already shown above); (b) Genus should have had access to Bariscan data; (c) Genus could have worked with Cimbar to validate Miti-Wite; and (d) Cimbar rejected Genus's request for Miti-Wite data due to its arrangement with Bracco, not due to infeasibility or impracticality.

i. Genus Should Have Had Access to Bariscan Data.

[redacted]

[redacted]

[redacted]

ii. Genus and Cimbar Could Have Validated Miti-Wite.

[redacted]

[33] [redacted]

[redacted]

[34] [redacted]

[redacted]

[35] Cimbar Website. https://www.cimbar.com/products/barium-sulfate/miti-wite-industrial/

[redacted]

[redacted]

iii. Cimbar's Purported Business Justification Is Contradicted by the Record.

[redacted]

[36] [redacted]

iv. Refusing to Deal with Genus on Miti-Wite Was Unnecessarily Restrictive and Unjustified.

Defendants assert the same procompetitive justifications for not validating Miti-Wite that they assert for their overall arrangement. Mem. 42. [redacted]

H. Genus Had the Ability to Obtain FDA Approval.

Defendants argue that Genus was not "financially or technically capable of obtaining FDA approval." Mem. 35. On the contrary, ample evidence (and inferences) supports Genus's ability to afford and secure approval, presenting a question of fact on this causation issue. RSMF ¶176-80.

Genus at any time could have sought investors to help finance efforts to secure FDA approval. RSMF ¶176 (Powers Dec. ¶32-33; PX23 Genus Cim. ROG 10-11, 13, 15) Genus had no reason to do this without ingredient data because it had no way to secure FDA approval. *Id.* Had Cimbar cooperated with Genus in 2017-2018, Genus would have pursued such an option. *Id.*[37] The record supports a reasonable inference that Genus could have attracted investors. Genus secured a contract with a major GPO (MedAssets) only a few months after it began marketing (and the same year it was founded), demonstrating its ability to attract business. RSMF ¶176, 199 A month later, Bracco deemed it a [redacted] RSMF ¶176. (PX38

[37] *See* PX23 Genus Cim. ROG 15 ("Had Cimbar worked with Genus when Genus requested data in and before late-2018, Genus would have pursued FDA drug approval for at least one of its products" instead of litigating against the FDA).

at 28959). Genus won a second GPO contract in April 2015. RSMF ¶199. In 2017, Bracco projected its [redacted]. RSMF ¶176 (PX69; PX05 Gehris Dep. 109:16-22). An investor would likewise have seen Genus's potential for growth upon securing FDA approval. And Genus's only debt consists of payables it pays in the regular course of business and loans from Ed Powers. PX23 Genus Cim. ROG 10.

Genus also had other resources beyond its operating income. RSMF ¶176 [redacted] And had Cimbar worked with Genus when Genus requested data for pursuing FDA approval – first in 2017 and then in late 2018 – Genus would have pursued drug approval for at least one of its products *instead* of incurring expenses litigating and lobbying to have BSSPs classified as medical devices. *Id*. [redacted]

Last year, Genus's projections put the cost of an Abbreviated New Drug Application (ANDA) at approximately $773,000 over three years if Genus had the application fee waived, paid for a DMF, and paid a supplier's fees for being an API manufacturer. SAF ¶242-43 (2023 Powers Dec. ¶36; PX310, P00085434 (calculations)). Genus could afford this without investors or

borrowing. *Id*. And this assumes Genus is not permitted to file an even less expensive type of NDA (a 505(b)(2) application), which remains possible. *Id*.

Although Mr. Powers framed drug approval as prohibitively expensive in his May 2019 declaration in the FDA litigation, several facts bear mention. RSMF ¶179. *First*, Genus had not approached any lending institution or potential investor to seek financing for approval, and thus his testimony did not factor in that option. *See* PX09 Powers Dep. 558:14-18 (Genus had not sought out such investors by Dec. 2022). *Second*, by this point Genus had sued the FDA, spending money that would have gone towards pursuing drug approval had Genus received Cimbar's cooperation. *Third*, if Cimbar had worked with Genus in 2017-2018, thereby providing a path to approval, Genus could have further evaluated its options then and concluded that pursuing drug approval could be done affordably. Powers Dec. ¶37. *Fourth*, Mr. Powers only projected that Genus would "in all likelihood" cease operations if forced at that time to pursue drug approval; he did not definitively say that Genus would shut down without exhausting all options. Genus would not have surrendered without a fight.

At his December 2022 deposition, Mr. Powers suggested that a route for seeking approval was feasible because it saved $200,000. *See* PX09 Powers Dep. 400:7-16; *see also id.* at 496:21-22 ("Upon ongoing analysis, I believe it's something that we could accomplish"), 499:2-3 ("I believe it's possible that we could achieve it"). Genus, however, had not approached any lending institution or potential investor seeking financing. *Id.* at 558:14-18. Thus, Powers clearly was not saying that an additional $200,000 cost would be prohibitive if Genus found an investor. RSMF ¶179; Powers Dec. ¶38.[38] Powers' May 2022 statement to a journalist likewise did not factor in

[38] He also noted applying for approval "might allow [Genus] to get back on a growth trajectory. The growth trajectory funds - - gives us additional funding to be able to cover our regulatory expenses." *Id*. at 542:9-

Genus finding an investor or Powers making further personal loans to his business; nor did he say that Genus would leave the market without exploring such options. RSMF ¶178; Powers Dec. ¶39.

Defendants cite a March 2022 email from Mr. Powers to Genus's lobbyist. But Powers did not say Genus was unable to pursue drug approval. The calculations he sent the lobbyist did not account for Genus finding an investor or taking additional loans from Powers; they simply compared FDA fees to Genus's gross profits. DX123. Powers wrote, "No company is going to enter the market or stay in the market when the cost of regulation exceeds the value of the product." *Id*. Genus needed its lobbyist to know (and tell legislators) the difficult position it would face if subject to the legislation it was fighting. RSMF ¶177; Powers Dec. ¶40. But Powers did not say Genus could not find, or would not pay, the amount required to stay in the market.

And in fact there is abundant evidence of Genus's determination to seek drug approval and its will to stay in the market. Genus's (unsuccessful) efforts to obtain information from Venator in 2016 and Cimbar in 2017 and 2018 to pursue this process, all before suing the FDA or filing this action, demonstrate its seriousness about drug approval. RSMF ¶192; SAF ¶224; PX21 Genus Br. ROG 7; PX23 Genus Cim. ROG 16; PX9 Powers Dep. 332:6-16, 351:11-352:14. Genus's fighting the FDA and lobbying Congress to create an easier path to approval (device clearance)—efforts Mr. Powers helped finance with personal loans to Genus (Powers Dec. ¶35)—demonstrate Genus's determination to stay in the market. [redacted] Powers has testified, [redacted], that Genus could afford a path to approval. *See* Powers Dep. 496:21-22, 499:2-3; RSMF ¶176-77; [redacted]

17, 679:6-9 ("[Y]ou're overlooking the second aspect to the evolution in our thinking, which was that we would grow once we got the regulatory burden lifted.").

[redacted] A reasonable jury can find Genus would have pursued all options to finance approval but for Defendants' conduct, including securing investors and taking further loans from Mr. Powers.

Notably, Bracco has itself [redacted][9] [redacted]

Defendants also claim Genus lacks the expertise to validate Miti-Wite or obtain approval with Bariscan. But such expertise can be retained. RSMF ¶185. Genus has identified a consulting firm and individuals to assist with the process. PX23 Genus Cim. ROG 14.[40] Genus would also rely on referrals from the law firm that successfully represented it in the FDA case, *id*. which advertises "Expertise in all things FDA."[41] Bracco's success securing FDA approval with Bariscan suggests Genus could do the same. Notably, Bracco did not even need to fund new clinical research to support its NDAs, which were backed entirely by existing medical and scientific literature. SAF ¶244 (PX19 Arrowsmith Rep. 22; PX12 Arrowsmith Dep. 249:20-251:9).

This case is miles apart from those where causation was found lacking or speculative. For example, in *Microbix*, where the plaintiff challenged an exclusive agreement between a monopolist and a supplier, the plaintiff had not even brought its products to market. 172 F. Supp. 2d at 698.

[39] *See* PX99 at 1828 ("If the application fees are not waived, it will be a significant barrier to Bracco's continued ability to manufacture and market these valuable products.")

[40] Both Cimbar and E-Z-EM have used this same firm, [redacted], in connection with FDA inspections. RSMF ¶161; PX100; PX49 at 0344.

[41] Hyman, Phelps & McNamara PC webpage, https://hpm.com/, last visited Sept. 16, 2023.

Moreover, the FDA had found the *supplier* in violation of good manufacturing practices (issuing *the supplier* a warning letter) and had banned the import of plaintiff's needed material. *Id*. at 686. The plaintiff could not have identified or corrected the supplier's deficiencies, and it lacked the "means or intention" to stockpile the material it needed before the FDA ban. *Id*. at 700-01. Thus, the plaintiff could not have realistically satisfied the FDA even with the deficient supplier's cooperation. In contrast, Genus has products on the market, and Cimbar is in good standing with the FDA. PX17 Auchincloss Rep. 9 ("Cimbar has never received a Warning Letter from FDA related to its barium sulfate API."). The key obstacles in *Microbix* do not exist. Genus's problem with the FDA is resolved if it can get approval, which is exactly what Defendants are preventing. And undercutting Defendants' causation arguments, a reasonable fact finder can conclude that Genus could have afforded and secured FDA approval with Cimbar ingredients and data.

I. Genus Can Show Damages and Entitlement to Injunctive Relief.

Defendants' argument that Genus cannot show damages cites their separate motion to exclude Dr. Marvel. Mem. 44-45. Genus thus incorporates by reference its response to Defendants' argument in its opposition to that *Daubert* motion. That opposition demonstrates that Dr. Marvel's opinions and testimony are admissible. Furthermore, Genus is seeking injunctive relief in addition to damages, and thus Defendants would not be entitled to summary judgment even if Genus's damages evidence were excluded.

III. Genus Can Prove Its Section 2 Claims.

Genus can prove its claims for monopolization, attempted monopolization, and conspiracy to monopolize under Section 2 of the Sherman Act. Defendants argue that Genus cannot show a

relevant product market or monopoly power, Mem. 50-51, 46-47, but Genus has shown both above.[42] Defendants also assert justifications for their conduct, but those justifications fall short.

A. Withholding Ingredients and Data Had No Business Justification.

Monopolization claims under Section 2 require a plaintiff to show that a defendant (a) possessed "monopoly power" in the relevant market and (b) willfully acquired or maintained this monopoly power by anticompetitive conduct (as opposed to a superior product, business acumen, or historical accident). *Insignia Sys.*, 661 F. Supp. 2d at 1056-57. Exclusive-dealing arrangements can be an improper means of maintaining a monopoly. *Dentsply*, 399 F.3d at 187. Willful maintenance of monopoly power can be shown where a defendant lacks valid business reasons for its anticompetitive conduct. *LePage's*, 324 F.3d at 163. Genus can make the required showing.

[redacted] As explained above in §II.F. and §II.G., [redacted]. *See Roxul*, 2019 WL 1109868, *18 (finding fact issue whether exclusivity agreements had procompetitive benefits given evidence that defendant overstated the impact of its investments).

[42] Also, the Court should not, as Defendants suggest, ignore the Eighth Circuit's statement that the relevant-market showing for a Section 2 conspiracy claim "need not be as rigorous" as for other claims. *Alexander v. Nat'l Farmers Org.*, 687 F.2d 1173, 1182 (8th Cir. 1982).

Defendants further cannot claim that their arrangement benefited consumers. It did not [redacted]

Evidence of Bracco's monopolistic intent further shows its lack of business justification. *See Geneva*, 386 F.3d at 506. [redacted][43]

Any benefit Bracco enjoys from anticompetitive conduct does not justify that conduct. "[A] defendant's assertion that it acted in furtherance of its economic interests does not constitute the type of business justification that is an acceptable defense to § 2 monopolization." *LePage's*, 324

[43] Specific intent to monopolize is not an element of a monopolization claim, although it is an element of attempt and conspiracy to monopolize. Defendants do not argue that Genus cannot prove specific intent to monopolize, other than arguing that their conduct had justifications. This evidence of intent helps rebut to Defendants' purported justifications.

F.3d at 163. Defendants' justifications are pretextual, which presents a triable issue. *See Graco Inc. v. PMC Glob., Inc.*, 2012 WL 762448, at *13-14 (D.N.J. Mar. 6, 2012) (finding triable issue whether justifications for exclusive dealing were pretextual on monopolization claim).

B. Genus Can Show Antitrust Standing and Causation with Respect to Bracco's Disinformation Tactics.

i. A Genuine Issue of Material Fact Exists as to Bracco's Inaccurate Statements Regarding Genus's Regulatory Status and Risk of Medicare Fraud.

Genus's Section 2 monopolization claim is premised, in part, on Bracco's [redacted]

"To bring a federal antitrust claim, a private plaintiff must demonstrate that [it] has suffered an 'antitrust injury' as a result of the alleged conduct of the defendants." *Insulate SB, Inc. v. Advanced Finishing Sys., Inc.*, 797 F.3d 538, 542 (8th Cir. 2015) (internal quotation marks and citation omitted). "Standing to sue under the Sherman Act 'requires an evaluation of the plaintiff's harm, the alleged wrongdoing by the defendant, and the relationship between them.'" *Sitzer v. Nat'l Ass'n of Realtors*, 420 F. Supp. 3d 903, 915 (W.D. Mo. 2019) (quoting *Gen. Indus. Corp. v. Hartz Mountain Corp.*, 810 F.2d 795, 809 (8th Cir. 1987)).

Defendants argue that Genus cannot prove Bracco [redacted] However, as Genus's response to Defendants' purported "facts" establishes, issues of material fact exist as to whether Bracco's statements were accurate.

See RSMF ¶202 (denying Bracco's assertion [redacted]

[redacted]

At the very least, the foregoing evidence creates a material fact dispute as to whether Bracco's [redacted]." Accordingly, Bracco is not entitled to summary judgment on Genus's Section 2 claim. *See Int'l Travel Arrangers, Inc. v. W. Airlines, Inc.*, 623 F.2d 1255, 1262–64, 1271–72 (8th Cir. 1980) (holding the plaintiff proved the Sherman Act's injury and causation requirements where, among other things, the defendant published a false,

misleading, and deceptive advertisement that was part of a course of conduct constituting an unreasonable restraint of trade).

IV. Defendants Are Not Entitled to Summary Judgment on Genus's State-Law Claims.

A. Defendants' Argument as to the Causation Element of Genus's Tortious Interference Claim Fails Under Missouri Law.

Defendants argue that Genus cannot prove the causation element of its tortious interference claim because [redacted]. Defendants are wrong on the law and the facts.

"To establish the third element of a tortious interference claim, the plaintiff must show that the defendant's acts induced or caused a *breach of the relationship*." *Fabricor, Inc. v. E.I. DuPont de Nemours & Co.*, 24 S.W.3d 82, 93 (Mo. Ct. App. 2000) (emphasis added). To determine if the defendant's acts caused a breach of the relationship, a "but for" test is applied, which requires a two-step inquiry: "'1) did [defendant] actively and affirmatively take steps to induce the breach; and, if so, 2) would the contract[ ] have been performed absent the [defendant's] interference?'" *Id*. at 93–94 (quoting *Cmty. Title Co. v. Roosevelt Fed. Sav. & Loan Ass'n*, 670 S.W.2d 895, 905 (Mo. Ct. App. 1984)).

Defendants make no argument as to the first step of the aforementioned test. Rather, they argue only that [redacted] Defendants' interpretation of Missouri law is incorrect. There is no requirement that a defendant [redacted]; instead, the element of causation is satisfied where there is evidence that a defendant "led [a party] to end its business relationship" with a plaintiff. *Fabricor*, 24 S.W.3d at 95. In fact, *Fabricor* squarely refutes Defendants' argument. There, the court of appeals affirmed a jury verdict for the plaintiff on its tortious interference claim

where there was sufficient evidence that the defendant-manufacturer caused the plaintiff's business relationship with a hotel chain to end. *Id*. at 93–95; *see id*. at 95 ("[T]he cumulative effect of all of DuPont's misrepresentations regarding Fabricor's financial ability led Marriott to end its business relationship with Fabricor after the completion of the Greensboro and Atlanta projects. Fabricor presented sufficient evidence on the element of causation."). As Defendants' causation argument is wholly premised on their misunderstanding of applicable law, the Court should reject it.

Nevertheless, the "evidence" that Defendants cite in support of their argument is also anything but "undisputed." In fact, the only supposed evidence that Defendants offer for their causation argument are hearsay statements that cannot be used to support summary judgment and which Genus otherwise disputed with specific cites to evidence that Bracco's interference caused Genus's business relationships with ROI and MedAssets to end. RSMF ¶¶198, 201. In sum, Defendants' causation argument collapses.

B. A Genuine Issue of Material Fact Exists as to Bracco's Use of Improper Means to Interfere with Genus's Contracts.

To defeat summary judgment, the fourth element of Genus's tortious interference claim requires it to show a triable issue of fact as to the "absence of justification" for Bracco's interference. *Nazeri v. Missouri Valley Coll.*, 860 S.W.2d 303, 316 (Mo. 1993). "Absence of justification refers to the absence of a legal right to justify actions taken." *W. Blue Print Co., LLC v. Roberts*, 367 S.W.3d 7, 20 (Mo. 2012) (internal quotation marks and citation omitted). Courts since *Nazeri* have interpreted it to mean that a plaintiff must allege and prove in all tortious interference cases that the defendant employed improper means. *Clinch v. Heartland Health*, 187 S.W.3d 10, 16 (Mo. App. 2006). Improper means are those that are independently wrongful, such as threats, violence, trespass, defamation, misrepresentation of fact, restraint of trade, or any other wrongful act recognized by statute or the common law. *Nazeri*, 860 S.W.2d at 317.

Defendants argue that Genus cannot prove the improper means element of its tortious interference claim because it cannot prove an antitrust violation. However, Genus has shown above a disputed issue of material fact as to Defendants' anticompetitive conduct. Genus has therefore established a genuine fact dispute as to Bracco's use of improper means to interfere with Genus's contracts with MedAssets and ROI. *See id.*

Further, as shown above, there is, at a minimum, a genuine dispute of material fact as to whether Bracco's statements [redacted] *See id.*; *see also Fabricor*, 24 S.W.3d at 96 ("Regardless of DuPont's reason for interfering with Fabricor's business relationship with Marriott, when DuPont made false statements with regard to Fabricor's financial ability to perform, it employed improper means in interfering in the relationship. Therefore, it is irrelevant whether DuPont was acting to protect its own legitimate economic interest, because under the law of tortious interference, one is never justified in using improper means to interfere with another's business relations.").

Genus has carried its burden on summary judgment to establish a genuine dispute as to the facts surrounding Bracco's use of improper means—and thus, its absence of justification—to intentionally interfere with Genus's contracts. Defendants are not entitled to summary judgment on Genus's claim for tortious interference.

C. Genus's Conspiracy Claim Survives Along with Its Other State Law Claims.

Because Genus's substantive claims survive Defendants' motion for summary judgment, so too does its claim for civil conspiracy. *Envirotech, Inc. v. Thomas*, 259 S.W.3d 577, 592 (Mo. Ct. App. 2008) ("Although conspiracy has its own 'elements' that must be proven, it is not a separate and distinct action and is predicated on proof of the underlying wrong.").

V. Genus Can Show Damages Relating to Citra Select and Viscasure Plus.

As explained in full in Genus's opposition to Defendants' motion to exclude the testimony of Dr. Marvel, incorporated here by reference, Genus can prove its damages relating to Citra Select and Viscasure Plus. Mem. 56. Genus summarizes its evidence here.

But for Defendants' conduct, Genus would be making stronger sales of its non-barium bowel-distension product, Citra Select. Defendants' conduct prevented Genus from pursuing FDA approval for its BSSPs. With FDA approval, Genus could enter into GPO contracts, as evidenced by its prior success securing GPO contracts and the GPOs' later rejection of Genus due to its lack of approval (i.e., the warning letter). *See* RSMF ¶196, 199; SAF ¶231-32; PX71 at 01326; PX39 at 07. Having GPO contracts would enable Genus to market its *non*-barium products, namely Citra Select, to GPO members. *See* PX03 Marvel Dep. 127:20-128:14 (describing this portfolio effect).

[redacted]

Likewise, but for Defendants' conduct, Genus would be selling Viscasure Plus. Defendants argue Viscasure Plus is "non-existent" and "hypothetical." But Viscasure Plus would simply premix two *existing* products that mix well: Vanilla SilQ MD and Viscasure. RSMF ¶151-52; Powers Dec. ¶49-53.

Genus sells a BSSP, Vanilla SilQ MD, that customers mix with other items to create home-

brewed swallow-study products that compete with Bracco's Varibar line. *Id.*; *see also* PX72 at 33985; PX73 at 00390; PX74 at 10465; PX18 Marvel Rep. 26; PX21 Genus Br. ROG 9.[44] Genus also sells Viscasure, a thickening agent [redacted]. Viscasure Plus would simply be a premixed product combining two things that already exist – Genus's Vanilla SilQ MD and Viscasure. Powers Dec. ¶49; *see* PX09 Powers Dep. 200:1-10 (Viscasure Plus is Viscasure plus barium). When Genus tested mixing Vanilla SilQ MD and Viscasure in 2016-2017 (PX23 Genus Cim. ROG 17), its testing showed the products mixed successfully and resulted in the proper viscosity to be used in swallow studies. Powers Dec. ¶50. [redacted] Essentially, Viscasure Plus already exists. *Id.*

Although Defendants' conduct has prevented it so far, Genus intends to make Viscasure Plus if it can secure FDA approval for its BSSPs (including Vanilla SilQ MD). *Id.* ¶50; PX09 Powers Dep. 200:25-201:14. Viscasure Plus cannot be dismissed as hypothetical, and Genus's damages are real. *See Shuffle Tech Int'l, LLC v. Scientific Games Corp.*, 2018 WL 2009504, at *2 (N.D. Ill 2018) (where "plaintiffs' theory is that defendants' wrongful conduct prevented them from getting into the market at all," expert's lost-profits projection was admissible (citing *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265-66 (1946)).

CONCLUSION

For all of the foregoing reasons, the Court should deny summary judgment.

[44] If Vanilla SilQ MD had FDA approval, Genus would make greater sales to swallow-study customers who mix home brews (*see* Powers Dec. ¶56). That fact alone supports Genus's claim for damages in the swallow-studies submarket.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing was emailed to counsel of record on September 20, 2023.

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